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INHALABLE PARTICULATE MONITORING PROGRAM QUALITY ASSURANCE PLAN

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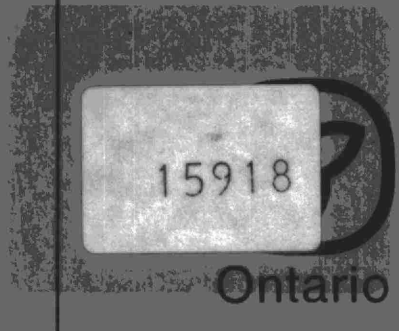

Ministry of the Environment
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ONTARIO MINISTRY OF THE ENVIRONMENT

INHALABLE PARTICULATE MONITORING PROGRAM
QUALITY ASSURANCE PLAN

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RÉSUMÉ

Le présent rapport expose en détail les politiques et objectifs à établir et les principes et procédures générales à suivre pour la collecte de données de haute qualité. Le Plan de contrôle de la qualité recouvre trois volets : 1) déterminer quelles composantes ministérielles doivent faire l'objet d'un contrôle de la qualité (soit les services régionaux, les services de laboratoire, et les services de gestion des données); 2) énoncer les objectifs et les particularités de chacune de ces composantes par rapport à l'objectif global du Plan de contrôle de la qualité; 3) mettre en relief les diverses activités nécessaires pour atteindre cet objectif global, soit : l'organisation interne et l'allocation des ressources, la collecte et l'enregistrement des données et les responsabilités en la matière, et l'établissement des méthodes de surveillance et des modalités à suivre en cas d'urgence.

DISCLAIMER

The information in this document has been subject to Ministry of the Environment peer and administrative review, and it has been approved for publication as an MOE document. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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In late 1983, an Inhalable Particulate Monitoring Program was established for the province of Ontario. The design of this experimental study is to quantitatively determine over time the mass and elemental concentrations of inhalable particulate matter (IP) at a number of urban and non-urban sites in Ontario. Inhalable particulate samples are collected at selected sites where total suspended particulate (TSP) measurements are routinely made. Monitoring site locations and descriptions are presented in Figure 1.

Inhalable particulate matter (IP), i.e., that fraction of ambient aerosol with aerodynamic diameters of less than 10.0 µm*, is characterized by two size-mode distributions. Fine inhalable particulate matter (FP) is that fraction of IP less than 2.5 µm while coarse inhalable particulate matter (CP) is that fraction of IP 2.5 µm to 10.0 µm. Fine particulate "arise primarily from condensation of vapour or chemical conversion of gaseous compounds to low volatility vapours that can nucleate" while coarse particulate "are generated principally by mechanical action" (Hopke, 1985).

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* The upper size limit for IP was established initially at 15.0 µm. In July, 1981 the U.S. EPA recommended that a 10.0 µm cut-point was more representative of the upper size limit of particulate entering the human respiratory tract. In late 1983, all Ministry of the Environment samplers were retro-fitted with 10.0 µm inlet heads.

Data generated by the Inhalable Particulate Monitoring Program will be used to evaluate:

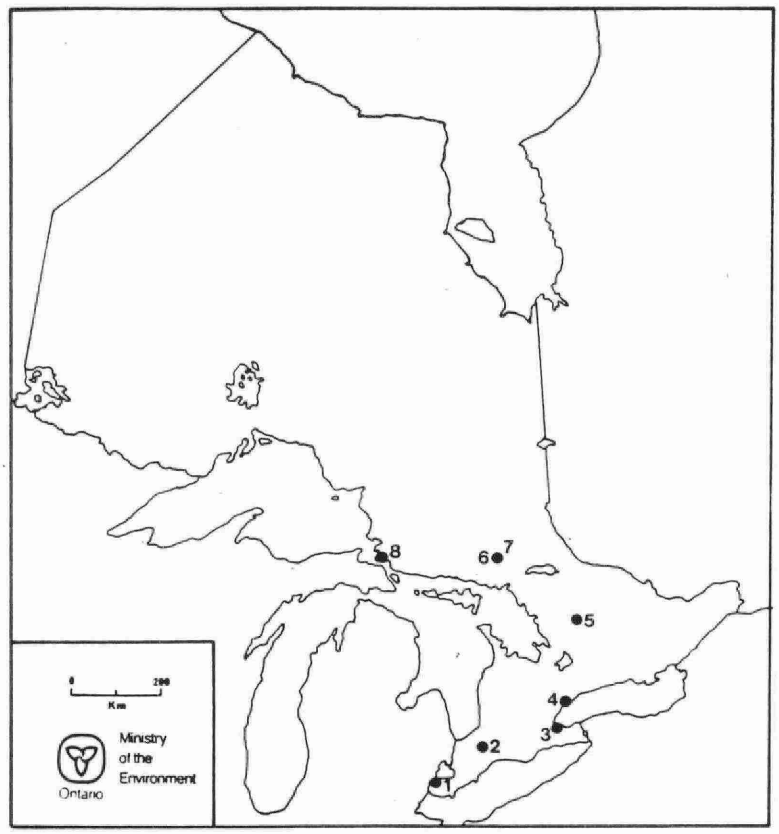
i) statistical relationships exhibited between TSP (i.e., aerosols with aerodynamic diameters less than approximately 100 μm) and IP as well as coefficient of haze (COH) with IP.

It may be possible to predict IP concentrations from TSP concentrations (for specific sites, under a variety of conditions) knowing, for instance, the average ratio of IP to TSP. Likewise, the COH to IP ratio may act as a real-time indicator for control action during heavy pollution episodes, in conjunction with the Ministry's Pollution Index (API) system.

ii) the spatial and temporal differences and similiarities in mass, size and chemical composition of IP.

iii) the instrumentation used to collect IP samples, with special emphasis on the assessment of the 10 μm inlet head's representativeness.

iv) source apportionment models proposed as a means of using IP information from given airsheds to characterize contributing point sources and source regions.



MAP NO.	STATION	LATITUDE (DDMMSS)	LONGITUDE (DDMMSS)	ELEVATION (M) SEA LVL	GRD LVL
1	WINDSOR	42.19.35	82.52.08	181.0	1.0
2	LONGWOODS CONS. AUTH.	42.52.58	81.28.52	238.0	2.0
3	HAMILTON BARTON ST.	43.15.32	79.50.35	91.0	4.0
3	HAMILTON BEACH BLVD.	43.16.31	79.46.52	77.0	4.0
3	HAMILTON COMMISSION DR.	43.16.18	79.46.48	78.0	4.0
4	TORONTO	43.39.50	79.23.06	104.0	15.0
5	*DORSET	45.13.23	78.55.53	323.0	3.0
6	SUDBURY	46.29.34	81.00.28	290.0	3.0
7	CAPREOL	46.42.09	80.55.08	102.0	1.0
8	SAULT STE MARIE A	46.31.47	78.21.38	183.0	4.0
8	SAULT STE MARIE B	46.31.50	78.21.15	190.0	3.0

* HEALTH AND WELFARE CANADA SAMPLER

Figure 1. Site Location Map (not all sites remain active)

v) estimates of respiratory tract particulate deposition. Miller et al. (1979) concluded that aerosols in the 2.5 to 15.0 µm size range tend to deposit in the conducting airways of the respiratory tract (tracheobronchial region) whereas aerosols less than 2.5 µm penetrate into the gas exchange areas of the lung (alveolor region). In addition to knowing the mass deposited, chemical analysis results provide toxicity parameters for risk assessment and other epidemiological research. Ultimately, a size-specific inhalable particulate standard, based upon the Inhalable Particulate Monitoring Program data can be promulgated by the Ministry of the Environment to effectively reduce particulate matter emissions in areas requiring attainment.

Inherent in the mandate of the inhalable particulate network's operations is the commitment to ensure that all data are scientifically valid, defensible, thoroughly documented and are reported with quality indicators. To achieve this goal, a Quality Assurance (QA) program, i.e., "a system for integrating the quality planning, quality assessment and quality improvement efforts of various groups in the organization to enable operations to meet user requirements at an economical level" (U.S. EPA, 1976), is considered by management to be a crucial element of the inhalable particulate program and accordingly, has been integrated into the network's operations to enhance its data credibility. It should be noted that the Ministry's central laboratory has implemented its own extensive QA program and is managed as an internal laboratory function. As such only a brief synopsis of the laboratory QA requirements which interface with the inhalable particulate program will be given here.

Proper implementation of the QA program requires the drafting of two 'framework' documents, whose rationale and required QA guidelines and activities not only serve to augment and complement existing standard operating procedures but also help minimize factors which could negatively affect data quality. By definition, these documents are:

i) a QA Program Plan - "an orderly assembly of management policies, objective, principles, and general procedures by which an agency or laboratory outlines how it intends to produce quality data" (U.S. EPA, 1980);

ii) a QA Project Plan - "an orderly assembly of detailed and specific procedures by which an agency or laboratory delineates how it produces quality data for a specific project or measurement method" (U.S. EPA, 1980).

To gain an overall perspective of the quality assurance effort, it is appropriate to describe only the QA Program Plan (hereafter called the QA Plan). The QA Project Plan (hereafter called the QA Manual) should be referred to for specific detailed quality control and quality assurance procedures designed to meet the objectives laid down in the QA Plan. Information concerning network instrumentation or the methods of performing routine or repetitive tasks (e.g., sample collection, analytical tasks) is provided in the Standard Operating Procedures and Technical Manual.

2.0 COMPONENTS OF THE QA PLAN

The function of the QA Plan is threefold. Firstly, it identifies those operational components within the inhalable particulate program which require quality assurance (broadly categorized as Field Operations, Laboratory Operations and Data Management Operations) and those non-operational components which are important quality assurance considerations. Secondly, the QA Plan states the quality assurance objectives of each of the network components and quality assurance considerations as they relate to the overall QA Plan objective. Thirdly, and most importantly, the QA Plan highlights the structural organization and resources, the data gathering/reporting functional activities and responsibilities, and the control systems and contingency procedures needed to ensure that the overall QA Plan objective is met.

The overall QA Plan objective is as follows:

- to ensure that the data quality characteristics of accuracy, precision, completeness, representativeness, and comparability are attained (through every effort possible) to given levels of acceptability through the design, description and implementation of quality control and quality assurance guidelines and procedures.

The data quality characteristics of accuracy, precision, completeness, representativeness, and comparability and their acceptance criteria are defined as follows:

i) Accuracy - the degree of agreement of a measurement (or an average of measurements of the same thing), X, with an accepted reference or true value, T, usually expressed as the difference as a percentage of the reference or true value, (100 X-T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system (U.S. EPA, 1983).

The term "accuracy" is somewhat of a misnomer for inhalable particulate measurement in the field, using this definition, since there is no absolute standard (i.e., a known volume and composition of IP) with which to challenge the monitoring equipment. Instead, "accuracy" must be indirectly inferred. It must be assumed that inhalable particulate is homogeneously distributed within the volume of air presented to the sampler and that the volume of air can be accurately measured in reference to a primary standard, such as a wet-test meter. Using this context, the volume of air determined by the inhalable particulate sampler must be within a ±10% agreement of the volume determined by the primary standard to be considered "accurate".

The determination of analytical accuracy can be readily accomplished using standard reference materials (SRM's) obtained from the U.S. National Bureau of Standards. The mass and elemental concentrations determined by the Ministry's laboratory must agree within ±10% of the values stated on the SRM's certificate of analysis to be considered "accurate".

ii) Precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is most desirably expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions" (U.S. EPA, 1983).

It cannot be assumed that inhalable particulate measurements taken by a particular instrument at a particular sampling point are reproducible over time. As such, it is necessary to conduct "precision" testing to assess the reproducibility of the measurement process. Since it is not possible to collect inhalable particulate samples simultaneously using the same instrument, a second colocated sampler of the sample type is used to assess the reproducibility or precision of the measurements. The mass and elemental concentrations of the colocated samples must be within a ±20% agreement of each other to be considered reproducible.

Analytical precision is to be determined by interlaboratory round-robin studies and by intralaboratory (within-run) replicate measurements. The acceptable level of precision for interlaboratory studies is to be established by the governing agency while intralaboratory precision levels are set by the Ministry laboratory's Quality Control/Quality Assurance Office.

iii) Completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.

A perfect rate of data capture would be ideal for any monitoring program. This rate, in reality, is considerably less because of certain inevitable sampling and analytical problems, notably instrumentation malfunction and downtime. Inhalable particulate data is to be considered complete and representative of the sampling effort for a particular site if 75% or more of the possible annual observations yield valid* mass and chemical concentration and deposition estimates. The 75% annual completion rate must be qualified, however, it is possible to attain this annual completion rate even though sampling in a particular season or seasons is not truly represented.

To qualify the annual completion rate, at least 67% of the possible seasonal observations must yield mass and chemical concentration and deposition estimates.

iv) Representativeness- the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition (U.S. EPA, 1983).

As the definition implies, "representativeness" is a generic term that can be used to describe various sources of error in inhalable

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* Data validation criteria are described in the Data Management Operations section.

particulate measurements. Sample representativeness is a function of two potential sources of error, namely, siting and sampling problems (e.g., sampler efficiency, sampler performance, particulate loss, sample degradation, condensation effects, contamination, etc.) Sampling problems are best assessed in terms of precision and accuracy. Therefore, "representativeness" will focus on siting only.

The sampling network is designed to assess the inhalable particulate realized at urban and non-urban sampling sites. All sites are to be located in areas representative of the conditions being measured (i.e., urban sites are to be located in urban situations; non-urban sites are to be located in non-urban situations) and must be free of local influences. For instance, the chemical composition and amount of inhalable particulate being deposited in an urban situation should be typical of the conditions within a 1 km radius of the sampling site. In a non-urban situation, where background concentrations are being sampled, the chemical composition and amount of inhalable particulate being deposited should be typical of the conditions within a 10 km radius of the sampling site.

Representativeness is addressed initially in the site selection criteria and evaluation. Continuous observation of land use and development is to be documented throughout the life of the sampling program and periodic external evaluation of a site's representativeness is to be done as part of a system's audit.

v) Comparability - a measure of the confidence which one data set can be compared to another.

"Comparability" is also a generic term, since it involves the assessment of accuracy and precision. The most familiar interpretation of "comparability" is the degree to which datasets obtained during inter-agency intercomparison studies are comparable. These datasets will be deemed comparable if statistical tests indicate there is no significant difference seen at given confidence levels (usually 95%). In order to test comparability, data is to be in consistent units (e.g., $\mu g/m^3$).

Another connotation of "comparability" involves analytical determination. It must be demonstrated that the analytical method of determination chosen for the monitoring program is the most feasible and is comparable to equivalent or superior methods of determination. For example, it must be demonstrated that results obtained by energy-dispersive x-ray fluorescence analysis (the method of choice in the inhalable particulate network) are comparable to the results obtained by instrumental neutron activation analysis or instrumental photonuclear activation analysis.

3.0 ORGANIZATION AND RESPONSILITIES

The Inhalable Particulate Monitoring Program is a cooperative venture involving the Air Resources Branch (ARB), the Laboratory Services Branch (LSB) and the Southwestern, West-Central, Central and Northeastern regional operations (SWR, WCR, CR, and NER, respectively) of the Ministry of the Environment. The program is administered by the Particulate Sampling Committee, whose membership is comprised of scientists from ARB and LSB as well as the Air Quality Assessment Chiefs from the aforementioned regions and from the Northwestern (NWR) and Southeastern (SER) regions. For matters relating to inhalable particulate, the Particulate Sampling Committee will be chaired by a scientist from ARB, who will function in the capacity of network operations and QA coordination, under the title "Network Coordinator".

Resources and support of the Inhalable Particulate Monitoring Program are as follows:

- Overall network QA management, field operations management, training, instrumentation procurement and development, and data management and reporting are the responsibilities of the Air Resources Branch. As such, the Air Resources Branch provides the material assistance to carry out these functions.

- Laboratory operations including sample reception, sample analysis and analytical data reporting are the responsibility of the Laboratory Services Branch. Funding for the analytical costs is the responsibility of the Air Resources Branch.

- Regional operations provide the manpower and technical assistance necessary to carry out all monitoring activities.

Decisions relating to the scientific direction, policy-making and progression of the Inhalable Particulate Monitoring Program are to be determined by concensus of the Particulate Sampling Committee at regularly (quarterly) scheduled meetings. The minutes of Committee meetings are to be distributed to its members for information purposes and as a follow-up to items requiring action. Committee members are to disseminate this information to their subordinates, where appropriate. In the interval between Committee meetings, discussions of policy matters will be communicated to and from the Network Coordinator to and from other members of the Committee.

An organizational chart, as it relates to the Inhalable Particulate Monitoring Program, is shown in Figure 2. This chart establishes the locations of QA responsibilities, the lines of communication and the internal flow of QA information. A brief summary of QA responsibilities for each position is also provided.

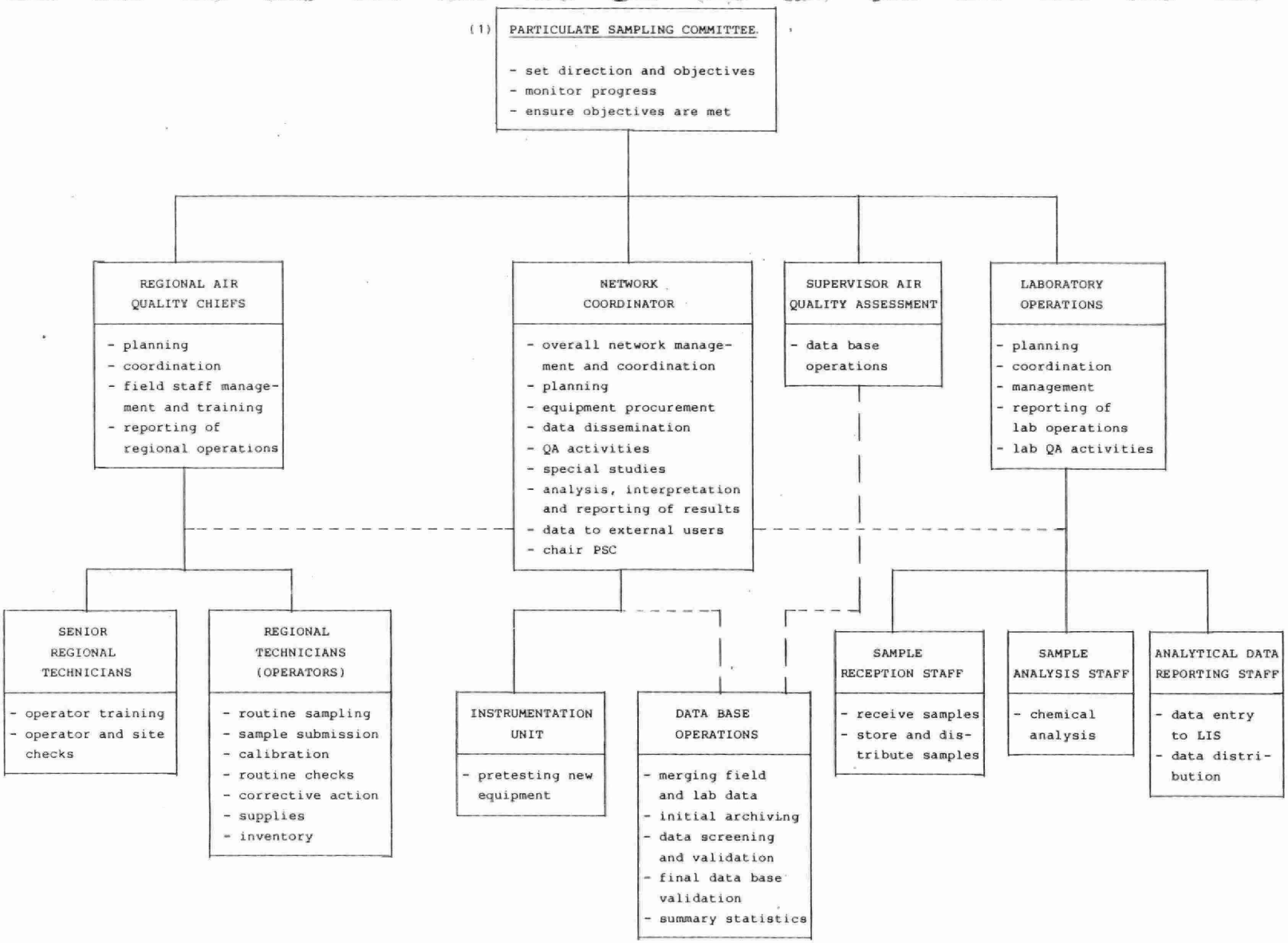
The success of the QA program and the sampling program in general depends on the following organizational requisites being met:

i) To maximize continuity within the network, sufficient manpower must be made available to carry out the work specified, within time and funding constraints.

ii) All personnel must know and understand the QA responsibilities of their positions and must possess the

necessary education, training, experience and commitment to fulfill their QA-related duties.

iii) Personnel qualifications, training needs and QA requirements as they relate to the Inhalable Particulate Program are to be identified and described in detail in the QA Manual.



(1) The Particulate Sampling Committee (PSC) consists of

A. Air Resources Branch representatives
   i) Network Coordinator (Chairman of PSC);
   ii) Supervisor SSRM unit, ARSP Section;
   iii) Supervisor of Air Quality Assessment.

B. The Air Quality Chief from each region;

C. Laboratory representation;

Figure 2. Organizational Chart

iv) Quality assurance reports (reports of data quality to data users and quality assurance reports to management) are to be issued regularly, preferably on an annual basis. These reports are to be reviewed and approved for distribution by the Particulate Sampling Committee. Any follow-up action identified in these reports are to be acted upon expeditiously by the Network Coordinator.

4.0 NETWORK OPERATIONS

The overall emphasis on quality assurance is focussed on the network operations segment of the Inhalable Particulate Monitoring Program. To permit an unambiguous evaluation of the project results, Network Operations is sub-divided to describe Field Operations, Laboratory Operations and Data Management Operations.

The mass and elemental integrity of all samples will be assured in the Network Operations provided:

i) well-conceived, scientifically-sound standard operating procedures and QA protocol are rigorously complied with by all personnel at all times;

ii) all personnel are thoroughly trained in their respective procedures and documentation of these techniques are readily available;

iii) dependable, state-of-the-art instrumentation is used in the network and preventative and remedial maintenance procedures are established to minimize downtime.

4.1 FIELD OPERATIONS

Accuracy, precision, completeness, representativeness and comparability are most sensitive to field operations. Field operations are the least controllable area of network operations because they are carried out by a large number of people under relatively limited control.

Field Operations address the following aspects:

i) Network Representativeness
ii) Field Instrumentation
iii) Sample Collection and Handling

4.1.1 Network Representativeness

To ensure network representativeness, monitors are to be located geographically in a manner which meets the network's design. Sites selected for monitoring must receive IP deposition representative in quality and quantity of the surrounding area and must match the criteria for which they were selected. General siting criteria for all sites are to be followed (e.g., avoidance of meteorological/ topographical anomolies, obstructions etc.). Any deviations from acceptable criteria are to be documented and data collected from these sites are to be closely scrutinized.

Ensuring that the site distribution meets its network objectives is the responsibility of the Particulate Sampling Committee, who have analyzed the IP data and have made an assessment of the site distribution for its suitability.

An essential element to assess representativeness is the documentation used to describe and evaluate all sites. A comprehensive listing of site selection criteria and site description is to exist for every site. This information is to be incorporated into a standardized site description form (see Appendix 1, QA Manual) by the Network Coordinator. This form is a modification of the National Air Pollution Surveillance site documentation (Environment Canada, 1985). The site description is to include the following:

i) location of the site including station name, station number, address (if applicable), latitude, longitude, UTM coordinates (Northing and Easting) and elevation above ground and above sea level. A topographical map is to be kept on file for each site;

ii) the start-up date of the station;

iii) the name, address and telephone number of the contact regional technician responsible for the site and of any alternates;

iv) scale of representativeness (i.e. neighbourhood, regional, etc.) and land use (i.e. industrial, commercial, rural, etc.);

v) a description of how to travel to the site and any other access information;

vi) a description of the electrical service at the site;

vii) a listing of all equipment installed at the site used for sample collection, including the name of manufacturers, model and serial numbers;

viii) a description of topography and a listing of other site influences;

ix) a description of human and vehicular activities near the site;

x) a site diagram indicating the position of the samplers, the location and type of surrounding windbreaks, buildings, roads, ground cover, obstructions, potential contamination sources in the immediate vicinity of samplers, electrical installations and compass points. The diagram is to be drawn to scale.

xi) location of stationary pollutant sources including distances and directions from the site. Description of any other potential sources such as nearby agricultural operations are to be included in this documentation.

xii) 4 site photographs are to be taken, in the direction of the 4 cardinal points and are to clearly show the instrumentation and its surrunding area;

xiii) a summary of the site including advantages, disadvantages and any deviations from siting criteria.

Monitoring sites may change to some extent over time. To determine whether existing sites meet siting criteria, a re-evaluation of every site is to be undertaken during an external QA systems audit. This re-evaluation is to consist of updating site documentation, including re-photographing all sites. A report reassessing the suitability of each site is to be submitted after the re-evaluation to the Particulate Sampling Committee for review.

Any site changes that occur between evaluations are to be immediately reported by the regional contact technician to the Network Coordinator. A "Site Change Notification" form (refer to QA Manual) is to be completed by the technician to document changes made to the site or its surroundings. The effect of any changes on the quality of

the data collected is to be evaluated as soon as possible by the Network Coordinator.

4.1.2 Field Instrumentation

The instrumentation used for sample collection represents the greatest potential for negatively affecting data quality since an instrument's capabilities and performance can affect accuracy, precision and completeness. The instrumentation used in a supporting function (e.g., calibration equipment, sample shipment and storage) can also affect data quality.

The instrumentation used in the field operations must be capable of meeting the following objectives:

i) the air sampler must be capable of collecting sufficient amounts of IP in both coarse and fine fractions for the chemical analysis of desired elements of interest, with the highest possible collection efficiency and the least possible level of contamination or interference.

ii) monitors capable of automatic sampling and little attendance in the field are the preferred mode of instrumentation. Manual samplers are acceptable for use at some sites, provided sufficient manpower is available for continuous operation.

iii) the sampling flow-rate must be calibrated to accepted standard methods with the highest possible accuracy.

iv) the instruments to be used for sample collection must be free of any environmental conditions which could impact

data quality (e.g., temperature, humidity or moisture build-up, dust levels, etc.).

v) to preserve the mass and chemical integrity of collected IP samples, shipping containers are to be chemically inert and are to be constructed in a manner which encourages shipment in an upright position and discourages rough handling.

The air sampler preferred for use is the automatic Sierra-Andersen dichotomous sampler (Model 245). Manual Sierra-Andersen air samplers (Model 244) are acceptable for use at sites normally visited on a regular, short-term basis (i.e., every third day). Both types of samplers fulfill the requirements of the first two objectives above. These instruments are to be housed in instrument shelters for protection from meteorological influences. 37 mm Gelman PTFE (Teflon) membrane filters are the preferred collection medium since they are chemically inert and they promote electrostatic attraction of inhalable particulate matter. Primary standards (e.g., wet-test meter, bubble kit) are to be used for static calibrations of the dichotomous air samplers. Secondary standards (e.g., mass-flow meter, calibrated flowmeters) are to be used for periodic checks of sample flow-rate. All samples are to be placed in disposable, 47 mm polycarbonate Petri dishes, which are to be mounted in chemically-inert carrying cases.

The dichotomous air samplers and their associated peripheral equipment are to be operated according to their design specifications outlined in their instrument manuals (which are to be ~~incorporated into the Standard Operating Procedures and Technical Manual~~ filed in a binder and kept with other program documentation). to assure that instruments operate according to their design specifications five quality assurance steps are to be implemented, namely,

procurement and pre-testing, inventory control, calibration, preventive maintenance and routine checking, and corrective action.

Procurement procedures, obviously, can only be applied to new samplers entering the network. If, and when additional samplers are required, every effort should be made to obtain the same type and model of sampler being used in the network. This is to ensure continuity and ease of operation of the network. If an equivalent type of sampler is desired, the following minimum procurement procedures should be followed:

i) detailed specifications of required instrument performance characteristics and manufacturing details (e.g., operating tolerance) are to be provided in the purchase order contract.

ii) detailed warranty specifications are to be stated in the purchase order. The purchase order must also demand a certificate of analysis for instrumentation or materials used for calibration or are critical to sample collection (e.g., filters free of impurities or artifact-promoting compounds). Detailed operating, maintenance and service guidelines, as well as schematic and mechanical drawings are to be made available upon purchase.

iii) upon receipt of an instrument, careful inspection is to be done to ensure that all specifications have been met. All equipment is to be tested by the Instrumentation Unit of Air Resources Branch for acceptance prior to deployment in the field. Procedures for acceptance testing are to be described in the Standard Operating Procedures and Technical Manual.

To maximize network data completeness, inventory control is essential. An inventory of spare parts is to be maintained at the Air Resources Branch and at each regional office to minimize interruption of sampling because of instrument downtime. Regional technicians are to take inventory of their spare parts and are required to submit a request for spare parts to the Air Resources Branch every six months. At no time should sampling be interrupted by the lack of spare parts.

Calibrations represent a QA activity for measuring and controlling the accuracy of the network management system. A calibration plan with recommended intervals for calibrating both measurement and test instrumentation is to be developed and documented in the QA Manual. Static calibrations performed using a primary standard or a secondary standard are to be done under environmental conditions seen while sampling. All samplers must be within an acceptable calibration range (as specified in the Standard Operating Procedures and Technical Manual) prior to installation and operating at the sampling site. After the calibrations are carried out, the calibration results are to be recorded on calibration log sheets. The regional technicians are to submit a copy of any calibration records to the Network Coordinator as soon as possible after the calibration has occurred. These results are to be added to the instrument history records at the Air Resources Branch. Upon review by the Network Co-ordinator, any significant changes in accuracy must be accounted for in the data entering the database. As a check on the calibration procedures, independent calibration audits are to be performed periodically by the Instrumentation Unit of the Air Resources Branch and by external auditors as part of their performance audit. The external auditor is to also verify that the audit results have been properly incorporated into the network database.

Increased instrument reliability will result if preventive maintenance and routine checking procedures are carried out on a regular basis. Instrument downtime decreases accordingly, thus, increased data completeness and accuracy are realized. Preventive maintenance procedures (e.g., cleaning, adjusting, testing) for minimizing failure of the sampling instruments or their parts are to be carried out semi-annually and are best accomplished on a rotating basis among sites. Simple routine checks should be done at each site visit (i.e., at least once per week) and at the beginning of each sample run. For example, inspection of rotameter settings are to be done on each site visit, while inspection of plunger O-rings are to be done at the beginning of each sample run. Both preventive maintenance procedures and routine checking procedures are to be documented in the QA Manual. Preventive maintenance is best done in the field so as to coincide with calibration procedures. For both preventive maintenance and routine checking, a summary check list is to be followed. Any changes to an instrument are to be recorded in the instrument's log book.

A corrective action plan scheme is essential for instrumentation. This scheme is to be documented in the QA Manual. The success of the corrective action depends upon the early detection of problems (through routine checking) and the response time taken by technical staff to rectify the problem. Once an instrumentation problem has been detected, it should be remedied on-site by performing the repair or by replacing the faulty instrumentation. There should be no interruption greater than two sampling days to effect these repairs. If the instrumentation problems are serious enough to warrant removal of the instrument to the regional office to effect repair, then the interruption should be no longer than five sampling days. All corrective actions are to be recorded in the affected instrument's log book.

4.1.3 Sample Collection and Handling

Sample collection and handling refers to all procedures to which inhalable particulate samples are subjected from the time they are collected from the monitoring instrument to the time they are shipped to the laboratory for analysis. The objectives of these procedures are twofold, namely: to collect, handle and transport the samples with no effects to their physical or chemical integrity and to obtain all necessary field measurements related to the collection of the samples. A number of QA requirements and activities have been incorporated into the various stages of collection and handling to meet these objectives, specifically:

i) All filters used for a sampling run are to be loaded into or unloaded from a sampling carousel at the regional office in an area which is clean, well-kept and free from dirt, dust or vapours (particularly cigarette smoke). Clean, disposable polyethylene or latex 'examination' gloves are to be worn during these procedures to avoid contamination. Care is to be taken to avoid touching the surfaces of the filters under any circumstances.

ii) The sampling carousel is to be placed inside a carrier device during transit to and from the sampling site to avoid contamination or exposure to the elements.

iii) Sample contamination by dirty instrumentation or wind-blown contamination is to be avoided through careful instrument cleaning and maintenance.

iv) A plastic-coated short-list of sample handling procedures is to be provided to each regional technician who carries

out the sample change. These procedural short-lists are to be referred to at the site and in the sample handling area to avoid any possible emission of handling steps.

v) A comprehensive field data form is to be completed for each batch of filters sampled, which would describe every filter (both coarse and fine) in that batch. The field data form will provide information on the description of the sample (sample number, site number, sample status, instrument number, etc.), a description of the sample's history (date exposed date removed sampling time, malfunction details, etc.) and a listing of applicable field comments and special remarks.

vi) All samples are to be hand-delivered (with their supporting documentation) to the laboratory in chemically-inert carrying cases within a prescribed period of time.

The QA activities outlined in the previous three sub-sections are by no means all-inclusive. The Field Operations component is intricately linked to a number of 'before-the-fact' QA mechanisms (routine 'special studies') and 'after-the-fact' QA mechanisms (non-routine 'special studies' and performance and systems audits) which are to be used to evaluate its performance and to assess that the procedures are well-conceived and scientifically sound. The following discussion will describe only routine (i.e. ongoing) special studies. Non-routine special studies and systems and performance audits, which are sporadic in nature, will be described in an upcoming section entitled "Other Network QA Considerations".

Routine special studies to assess precision and accuracy in the Field Operations are to include:

i) Colocating air samplers at (at least) one sampling site within each region for a fixed period of time (one year is preferred). Rotation of the colocated sampler(s) is to occur within each region until each site is covered.

ii) A pair of coarse and fine 'passive' field blank filters are to be submitted from each batch of filters used during a collection period to assess background contributions of IP.

iii) A pair of coarse and fine 'handling' blanks are to be submitted quarterly from each site.

4.2 LABORATORY OPERATIONS

The coordination of the analysis of inhalable particulate samples is the responsibility of the Inorganic Trace Contaminants (ITC) Section of the Laboratory Services Branch at Rexdale, Ontario. The two major functions of the laboratory operations are to carry out and report the mass and elemental analysis of inhalable particulate samples generated by the monitoring activities and to support the field operations through routine quality control procedures and special studies activities.

To meet these objectives, the laboratory must follow stringent quality assurance and quality control* procedures (which are to be documented in detail in the QA Manual) to produce data of known precision, accuracy and comparability. A number of QA considerations are implicit with this need, namely:

i) Specific quality control and quality assurance procedures are to be designed, documented and carried out to determine the precision, accuracy and comparability of the laboratory results. Acceptable limits of precision, accuracy and comparability are to be defined and documented.

ii) 'Function' and 'control' checks are to be systematically performed on both a real-time and long term basis to ensure that acceptable operating conditions are maintained and to identify situations which do not meet QA objectives. Corrective action procedures are to be followed to rectify 'out-of-control' situations.

iii) The laboratory must produce data within a reasonable time frame and in a format suitable for subsequent data manipulation, screening and analysis after receipt of the samples.

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* 'Quality control' is defined as "the routine application of procedures for obtaining prescribed standards of performance in the measurement process" (U.S. EPA, 1983).

The elements of laboratory quality assurance which can directly affect the precision, accuracy and comparability of the inhalable particulate data are:

i) Sample Measurements
ii) Laboratory Sample Handling
iii) Support of Field Measurements

4.2.1 Sample Measurements

The mass of inhalable particulate samples is to be determined gravimetrically, using an electrobalance. The electrobalance must be extremely sensitive (i.e., it must be capable of detecting weight changes as small as 100 nanograms) and must be capable of transcribing and recording the mass determination electronically. The instrument preferred for use is the Cahn Electrobalance (Model 25). The elemental determination of inhalable particulate is to be done in a non-destructive (non-digested) manner since re-analysis may be required. To measure the thin film of inhalable particulate deposited on a membrane filter, the most feasible non-destructive method is energy-dispersive X-ray fluorescence (EDXRF). As such, ITC uses an EG&G Ortec (Model EEDS2.TEFA) analyser for elemental analysis of inhalable particulate samples. The instruments used for each type of analysis are to be operated according to their design specifications outlined in their instrument manuals (which are to be incorporated into the Standard Operating Procedures and Technical Manual).

The systematic application of quality control procedures on both a real-time and long-term basis is required to evaluate data quality. These procedures consist first, of 'function' checks (which verify the sample validity at the time of analysis and confirm that the instrument or analytical procedure was operated correctly and

under proper conditions) and, secondly, 'control' checks (which provide a measure of the variability of the results obtained in terms of precision and accuracy and identify deteriorating or "out-of-control" conditions as they develop to ensure that they are rectified immediately).

Function checks are to be performed at the analyst level and are to include:

i) Conditioning of the inhalable particulate filter prior to analysis. This would consist of storing filters in a temperature/relative humidity controlled chamber which is free of vapours (particularly cigarette smoke) as well as the elimination of static electricity from the filters by exposure to a weak radioactive source.

ii) Verification of the samples mass and elemental integrity. To verify mass determinations, every twentieth filter is to be reweighed at the end of a submission's weighing run. When abnormally high or abnormally low results are seen (in comparison to seasonal highs and lows), the entire submission is to be reconditioned, then reweighed. If these anomalous results persist, the submission is to be reweighed again but only after the submission of filters has undergone EDXRF analysis. In addition, the sample must be free of physical imperfections (e.g., thumbprints, holes in the filter, etc.) to ensure its integrity. No analysis is to be performed on "flawed" filters.

iii) Ensuring that the instrument is working prior to operation. All instrumentation is to be properly warmed

up and instrument drift and noise are to be checked and documented.

iv) Adjustment for zero, span and operating ranges (if required).

It is important that the system be reliably maintained through proper service and maintenance procedures to minimize and quantify the variability observed between runs.

Control checks are to be performed by the analyst as part of his routine analysis procedures and by laboratory QA personnel without the knowledge of the analyst. The selection of the types of control checks to be used and their frequency of use is to be determined by the Laboratory QA Manager for each analytical procedure. Control checks are to consist of:

i) Instrument calibrations, which are performed to identify the instrumental response to "known" mass and elemental loadings in order to relate instrument response to the corresponding mass and elemental loadings of "unknown" samples. The accuracy of the electrobalance and the EDXRF analyser are to be challenged regularly (i.e., day-to-day, run-to-run) via repeated analysis of quality control standards (weight sets and standard reference materials) over the range of expected instrument response. If a calibration cannot be confirmed, then corrective action must be undertaken (i.e., recalibration) to bring the calibration back into control before the analytical run commences.

ii) Submission of QC samples ('blind' samples, laboratory blanks, or real inhalable particulate samples) at various stages of the analytical stream is required to assess the precision and accuracy of the system as well as the detection of analytical bias or introduction of contamination. Once again, the selection of the type of control samples to be used and the frequency with which they should be analyzed is to be determined by the Laboratory QA Manager.

iii) The results of the analysis of QC samples to be plotted on a real-time basis against historically determined statistical limits for "warning" and "out-of-control" situations. This is done by calculating the mean ($\bar{x}$) and standard deviation (σ) of a number of repeated measurements. "Warning" limits are to be set at $\pm$ 2 σ and the "out-of-control" limits at $\bar{x} \pm 3\ \sigma$. Warning and out-of-control limits are to be periodically recalculated to include recent measurements in the statistical calculations. Results which exceed the control limit values would indicate that re-analysis is needed. Results of this type are to be appended with an appropriate lab remark code.

iv) The ITC Section is to regularly participate in inhalable particulate interlaboratory round-robins to assess accuracy and comparability.

v) The validity of the results produced by ITC is to be assured. This would require checking samples to see if they are identified and labelled as described on the Request for Analysis form. This check is to be done before samples are entered into the analysis queue. The

laboratory supervisor must screen all data sets before releasing the data to the Sample Information System (SIS) to ensure that all requested analysis were performed, that data transcription errors or omissions had not occurred and that unreasonable or obvious errors were not recorded in the data sets.

4.2.2 Laboratory Sample Handling

The potential for sample contamination, mishandling or degradation within the laboratory is to be kept to a minimum by following established sample custody and sample storage procedures. Sample custody procedures are needed to ensure the progression of all samples through the laboratory analysis stream from sample reception, through conditioning of the filters prior to analysis, the analyses themselves and the final archiving of the samples. A system for monitoring and recording the sample custody elements within the laboratory is to be implemented and is to involve the use of a sample custody form (see QA Manual). This form is to include the following information: sample identification (sample/analysis number), date received at the laboratory, receiver's signature and comments, date entered into the laboratory system, analyst identification, the date that all analyses were completed and the date submitted for long-term storage (indicating the storage location).

Specific activities for sample custody and sample storage are listed below:

i) upon receipt at the laboratory, all samples are to be visually inspected for physical defects and to ensure they are properly labelled and arrive with their supporting documentation;

ii) the laboratory sample custody procedures including logging the samples into the laboratory system and the issuing of a sample custody form are to be initiated;

iii) all supporting documentation (field sheets, Request for Analysis forms and Lab Submission forms) are to be filed and kept on hand for easy reference;

iv) all samples are to be stored at 20°C and greater than 50% relative humidity in an area free of interferences (e.g., cigarette smoke), preferably in the weighing room until they move onto the next sample custody area;

v) any corrective action procedures required as a result of problems observed at the sample reception stage are to be done;

vi) reasonable time limits are to be established for each analysis stage to ensure that sample analyses are completed within the prescribed timeframe. Submissions are to progress through the series of analysis stages as a whole and not as individual filters. For instance, all filters from a particular submission are to be weighed consecutively and then either sent back for reconditioning until EDXRF analysis is possible or are sent for EDXRF analysis directly, but only as a group or submission of filters. This type of scheduling will take into account the number of samples that can be analysed within an analytical run and will prevent having too many filters taken out of their conditioning environment waiting for analysis;

vii) once all analyses have been completed and the data have been screened and released, the filters are to be retained for possible re-analysis. Long-term storage of the filters will, therefore, take place at the laboratory. The filters are to be kept on-hand until they are no longer required, i.e., a period deemed acceptable to the Particulate Sampling Committee (e.g., two years), and are then to be disposed.

4.2.3 Support of Field Measurements

Two additional responsibilities of the Laboratory Operations in support of Field Operations are participation in non-routine "special" studies and preparation of the filters prior to deployment in the field. The special studies activities will be described in an upcoming section entitled "Other Network QA Considerations".

The filters used for sample collection are to have their tare weight determined by the ITC section of the central laboratory prior to exposure in the field. This effort ensures consistency in weighing and provides a good measure for the assessment of accuracy. Tare weight determinations are to be used to calculate the loading of inhalable particulate after exposure in the field. All filters are to be handled in the same manner prior to exposure in the field as they are after exposure (i.e., they are to be conditioned prior to analysis, same custody procedures, etc.). Batches of filters are to be made available to the various monitoring regions at least two weeks before the next sampling run is scheduled to commence, to avoid last-minute notification for filters.

4.3 DATA MANAGEMENT OPERATIONS

The function of the Data Management Operations is to correctly and efficiently compile, screen and validate, transfer, report, and store the data generated by the Inhalable Particulate Sampling Program. The data management system is broken down into the following modules:

i) Data Collection and Entry
ii) Data Management
iii) Data Screening, Validation and Reduction
iv) Database Structure
v) Data Reporting
vi) Standard Data Analysis
vii) Provision of Data to External Users

The data management system and its associated QA activities are shown in Figure 3.

4.3.1 Data Collection and Entry

The data collection and entry system provides the means for transferring the sampling and analytical information from the field and laboratory into the preliminary (working) database as quickly and efficiently as possible. All relevant information is to be reported at each stage of the process and errors in data recording and transfer are to be minimized through the use of standardized data coding forms, transmittal procedures and data entry procedures.

Data collected at the Field Operations level are to be documented on a standardized field information form (see QA Manual). This form is designed to ensure that all information is easily

recorded in the field and can be readily extracted from the form into the working database. This form is to include information concerning each sample submitted, namely: sample description (sample number, site name and number type of sample collected, instrumentation used, etc.), sample history (sampling date and time, elapsed sampling time, flow rate, malfunction details, calibration and routine check information, etc.), field comments, i.e., factors which may have influenced the integrity of the sample (instrument problems, contamination, non-standard sampling period or sampling time, unusual occurrences, etc.), and special remarks (elaboration of previous entries). The form used for recording field information is to be a multiple-copy type, which aids in reducing the possibility of data transcription errors. The original copy is to accompany its respective samples to the laboratory while one carbon copy is to be retained by the regional technician for easy reference and the final copy is to be forwarded to the Network Coordinator for scrutiny.

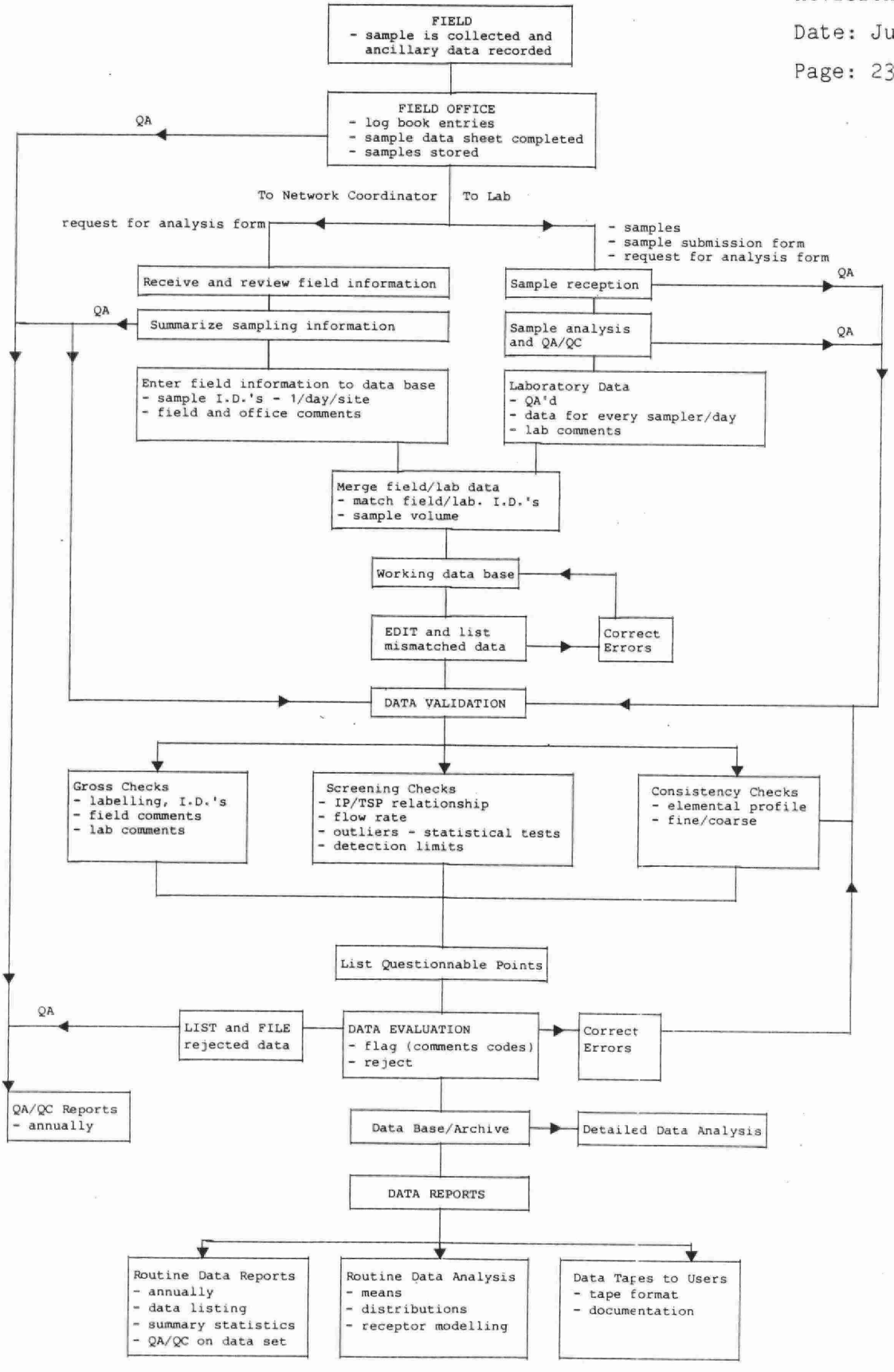

Figure 3. Network Data Handling Structure

The quality assurance procedures associated with the collection of field data consist of ensuring that, i) the regional technicians are properly trained in the data recording procedures; ii) they record all pertinent information; and iii) periodic evaluations of the system used to record and transmit the information are carried out.

The objective of the laboratory data management system is to provide a quality controlled set of analytical results (either an analytical result and/or a coded response for each sample submitted) that can be merged with the field sampling information for subsequent data screening, validation and reduction. A number of preliminary QA checks are to be done before the analytical data are released from the Laboratory Information System (LIS) into the Sample Information System (SIS) and the Air Quality Information System (AQUIS). These checks include, i) verifying sample labelling and matching field sheets with samples; ii) ensuring an analytical record exists for each sample described on the field sheets; iii) checking for obvious transcription errors; iv) checking the laboratory data printout against original field sheet information; v) identifying values that exceed seasonal upper limit values (these samples are to be automatically re-analysed to verify the result before the submission is approved for release); and vi) ensuring that any missing or coded results are explained. Data are to be transferred by submission from LIS and AQUIS after these checks have been performed.

4.3.2 Data Management

The management of the inhalable particulate database is the responsibility of the Database Scientist working through the Air Resources Branch (currently, an external consultant is used).

Management of the database includes:

i) entering field data into the database;
ii) merging and editing field and laboratory data;
iii) creating a working database;
iv) data screening, validation and reduction;
v) final data archiving;
vi) data reporting.

This segment will discuss data management up to the creation of the working database. The other aspects of the data management are described in detail in Sections 4.3.3. to 4.3.7.

The field information sheet forwarded to the Network Coordinator is to be scrutinized for incomplete data entries and labelling errors and legibility. This preliminary review at the data reception stage allows for the correction of omissions and errors in the data forms while the regional technician is still familiar with the submission.

The merging of field and laboratory data is to be carried out by the Database Scientist through the Ministry's computer facilities. This would include the addition of TSP mass data into the IP database. A software package is to be developed to match the field and laboratory data for all samples and to incorporate them into a single working database. This program is to list samples which do not have matching field and laboratory data and is to have the capability of correcting and editing the working database. After all data have been matched and all sample identification errors and omissions have been corrected by the Database Scientist, the working database can then be subjected to data screening, validation and reduction programs.

4.3.3 Data Screening, Validation and Reduction

Data screening and validation techniques are to consist of a set of automatic (computerized) procedures designed to identify and evaluate questionable data (these data screening and validation techniques are documented in detail in the QA Manual). The computer data screening and validation procedures are to be used to compare all data to a set of predetermined standards (e.g. standard sampling period or sampling time, upper limit checks, fine/coarse mass ratios, elemental ratios, IP/TSP mass ratios, etc.) and to list any data which do not conform to the prescribed screening and validation criteria. Based upon these results, the data will either be objectively accepted as stated or will be accepted with qualifications. If the latter is true, the affected record will be appended with an appropriate office comment. At this point in the Data Operations, no data will be rejected (invalidated) from the database. The only reduction in the database will be the sequestering of passive sample records, after they have been used for background loading corrections.

4.3.4 Database Structure

For quality assurance purposes, the data archiving system must provide means of ensuring that a complete, correct data set is maintained, that it is secure (i.e., restricted access for editing) and that it has the capability of retrieving QA/QC information for all data collected. The database must be in a standardized format such that data access and manipulation routines may be developed to extract and sort subsets of data for data analysis purposes as well as for generating data tapes for authorized users. Inherent with the archiving system is the need to restrict access to editing and deletion routines only to authorized personnel.

4.3.5 Data Reporting

Data reports are to consist of inhalable particulate concentration and deposition listings, annual data summary statistics, and QA/QC data summaries. Data is to be released within the Ministry in report form only after its quality has been assessed and documented. The data listing and annual summary statistics reports are to be issued yearly, within nine months of data collection. QA/QC data summaries are to be released bi-annually.

All reports are to be in a format that is easily readable. For example, the field information and data for each parameter for a particular site is to be condensed on one or two pages, column titles are to indicate the parameter being reported and the units of measurement, and all remark codes are to be clearly explained. All reports are to include site descriptions and descriptions of analytical limits of quantification.

4.3.6 Standard Data Analyses

Standard data analyses are to be done by the Database Scientist of the Air Resources Branch and are to include calculations of daily, seasonal and annual concentration and deposition and data distribution for all species on an individual site, regional, and network basis. Collaboration between the Air Resources Branch and the monitoring regions will determine which data are used in the data analyses. The exclusion of unreliable data must, however, be based on objective rejection criteria (e.g., severity of field comments).

Detailed data analyses (e.g., chemical mass balances, factor analysis, target-transformation factor analysis, etc.) are to be done by both the Air Resources Branch (to determine temporal and spatial

trends of the network as a whole and in relation to development and verification of source-receptor modelling) and the monitoring regions (to determine regional-scale trends and episodic phenomena) after the data verification process has occurred.

4.3.7 Provision of Data to External Users

Since a demand for the network's inhalable particulate data is anticipated, screened and validated data are to be made available to external users (i.e., non-Ministry agencies) upon demand, either in printed report form or on magnetic tape. The external users are to receive a well-documented description of the data file format and contents (parameter format, units of each parameter and description of remark codes) to facilitate easy extraction. The documentation is to also include a synopsis of the network operating procedures and QA/QC procedures, site descriptions, data screening and validation techniques, description of the analytical limits of quantification, a summary of the network's annual data summary statistics (e.g., range of values, seasonal averages for each parameter, etc.) and a disclaimer stating it is the discretion of the user to include or delete questionable data in their working database (since the data provided to external users is only qualified, not invalidated).

5.0 OTHER NETWORK QA CONSIDERATIONS

The QA considerations to be presented in this section fall outside the considerations of previous sections or extend beyond one section into several. All have been peripherally mentioned, yet warrant more detail. Other network QA considerations are:

i) Training and Upgrading;
ii) Corrective Action;
iii) Network Documentation and Document Control;
iv) Non-Routine Special Studies;
v) Systems and Performance Audits;
vi) Quality Assurance Reporting.

5.1 TRAINING AND UPGRADING

It is of utmost importance for network personnel to be updated and upgraded in their training to account for changes and/or additions in their QA responsibilities. This is accomplished in the following manner:

i) all network personnel are to have a complete set of the Standard Operating Procedures and Technical Manual on hand for quick, easy reference. If a new procedure is to be implemented in the network, it is the responsibility of the Network Coordinator to update and distribute copies of this procedure for inclusion in the manual, as described in Section 5.3 (Network Documentation and Document Control).

ii) the regional technician is to become familiarized with each new procedure and must be capable of performing it. If necessary, the Network Coordinator is to observe the regional technician perform this procedure to ensure it is done correctly.

iii) unless required as a emergency measure, new operational procedures are to be implemented only at specified times throughout the year, notably after "technician" meetings where the new procedures have been explained. Such consolidation of changes helps to prevent haphazard implementation and ensures that all network personnel are receiving consistent training and upgrading.

iv) regular (at least weekly) communication is to occur between the Network Coordinator and the ITC Supervisor and the Network Coordinator and the senior regional technicians to ensure that the operating system is progressing smoothly and that notification of any problems is promptly served and acted upon.

In addition to providing training procedures, "technician" meetings allow for vital communication and feedback to take place. These meetings are to be held semi-annually at the Air Resources Branch and are to be attended by the Network Coordinator, regional senior technicians and the regional technicians responsible for the operation of sampling sites.

Training inadequacies are sometimes detected during routine supervisory checks or during external QA audits. Unsuitable or

insufficient initial training or upgrading and follow-up are the primary reasons for training inadequacies. In addition to training inadequacies, poor attitude or lack of interest in the sampling program and unsuitable operating procedures may be observed as problems leading to a need for upgrading. It is the responsibility of the Network Coordinator to bring these inadequacies or procedural problems to the attention of the respective Air Quality Assessment Chiefs, who are to act upon these problems. If necessary, the Network Coordinator is to offer any technical assistance needed to correct problems identified.

The discussion above is relevant to personnel already in the network. When new personnel enter the network, initial training and follow-up training is to be done. All new technicians are to become familiarized with all network documentation and are to receive thorough training under the supervision of the senior regional technician, with at least two weeks of on-the-job "hands-on" experience.

5.2 CORRECTIVE ACTION

Inherent with a monitoring program are sampling problems which may result in lost, inaccurate or imprecise data. Most problems, such as instrumentation failure, can be dealt with using an immediate corrective action scheme. Systematic problems, however, are often detected only after non-routine special studies or system and performance audits have been conducted. In either situation, to ensure that problems of non-conformity within all network components are detected,

eliminated and reported on in a timely manner, a "closed-loop" corrective action scheme, for short-term and long-term problems, are:

i) define the problem;
ii) assign responsibility for investigating the problem;
iii) investigate and determine the cause of the problem;
iv) determine the corrective action to eliminate the problem;
v) assign and accept responsibility for implementing corrective action;
vi) establish the effectiveness of the correction action and implement the correction;
vii) verify that the corrective action has eliminated the problem.

All corrective action plans are to be documented in the QA Manual. For immediate corrective action, it should only be necessary to consult checklists, control charts, trouble-shooting guides and instrument manuals for the corrective action to be performed on-the-spot. If the problem is serious enough to affect data completeness or data accuracy (i.e., it can't be fixed in the field), the problem should be corrected at the regional office. No more than 3 sampling days should pass before the problem is rectified and sampling resumes. The success of the corrective action scheme hinges on the early detection of the problem and the response time needed to correct the problem. Long-term corrective action requires that the sequential, methodical approach be applied to systematic problems because they can have a substantial impact on the network's data quality as a whole. It is required that a Corrective Action Log form (see QA Manual) be prepared by the Network Coordinator for each non-conforming situation as it is identified.

5.3 NETWORK DOCUMENTATION AND DOCUMENT CONTROL

Documentation necessary for the proper operation of the network is essential and must be properly produced, updated and distributed on a regular basis. A document cataloguing system, which lists document type, document identification number, title author(s), date of publication, dates of revisions and a user distribution list, is to be maintained by the Network Coordinator. This listing is to be incorporated into the QA Manual.

Any changes in operating procedures are to be immediately updated and distributed to all personnel. The page indexing format (see, for example, the top right hand corner of this page) is to be used for easy insertion of revised, updated or additional pages into existing documents. Each major section should begin on a new page so that the revision of single sections can be done without affecting other sections. When new pages are revised, they are to be substituted for the old and a notation is to be made in the Table of Contents.

5.4 NON-ROUTINE SPECIAL STUDIES

Additional or modified operating procedures are to be initiated on a non-routine basis to investigate and quantitatively assess site-specific, operation-specific, or network-wide phenomena or peculiar data trends as they affect precision, accuracy, completeness, representativeness and comparability. These "special studies" can

also be considered as part of long-term corrective action or as a follow-up to systems and performance audit recommendations.

Special studies are to be initiated as soon as possible after they have been identified or strongly suspected, but only after Particulate Sampling Committee approval has been given. Special studies must be carried out under the strictest of quality control/ quality assurance procedures. As such, each special study must be documented in terms of its quality assurance activities and structure. In essence, each special study is to have a condensed QA Plan, composed of:

i) a description of the study and its objectives;
ii) a project schedule;
iii) an outline of responsibilities;
iv) a description of the sample collection, handling and analysis procedures, data screening and validation procedures and QA/QC procedures specific to the special study;
v) a data reporting scheme.

5.5 SYSTEMS AND PERFORMANCE AUDITS

Audits to assess the quality of the data and the collection and measurement processes as are to be carried out on a routine basis by auditors independent of the monitoring network. These audits are to consist of systems and performance audits to qualitatively and quantitatively (respectively) determine i) whether the quality of the network's operations comply with desired standards of operation,

accuracy, precision, representativeness, completeness and comparability ii) whether the existing operations are sufficient to maintain those standards and iii) whether the Inhalable Particulate Monitoring Program's QA program is satisfactory for assuring the standards. To meet these objectives, an external auditor is to evaluate the representativeness of the sites in the network (50% of the sites per audit), assess the collection and measurement systems of the network and assess the data management system. External audits are to be done bi-annually if they are deemed warranted by the Particulate Sampling Committee. Annual internal performance audits of the Field Operations component are to be done by the Instrumentation Unit of the Air Resources Branch and the performance of the Laboratory Operations component is to be assessed by the Quality Assurance Office of the Laboratory Services Branch.

The external auditor chosen to carry out the audits should be experienced and knowledgable in the fields of quality assurance and inhalable particulate monitoring. The design of the audit depends upon the guidelines given in the QA Plan. A specific design of the audit is to be produced by the auditors and is to be evaluated by selected members of the Particulate Sampling Committee before it is carried out to ensure that it is suitable for network purposes. A final auditor's report is to be prepared and submitted to the Particulate Sampling Committee upon completion of the audit. The report is to contain the results of the systems and performance audits including details of the site evaluations, technicians assessments, the results of the evaluation of the data management system. Weaknesses, strengths and recommendations generated by these evaluations are to be reported in detail. Any previous audit recommendations are to be followed up by the auditor to determine if these recommendations

were implemented, and if not, why they were not implemented. A synopsis of audit results are to be incorporated into the annual QA reports prepared by the Network Coordinator.

Since external audits are essential to the success of the QA Program and the Inhalable Particulate Monitoring Program, in general, they warrant further elaboration. The requirements to verify, examine and evaluate that site representativeness and the collection, measurement and data management components have been properly documented and effectively implemented in accordance with specific objectives are given below.

To assess site representativeness, the accuracy and completeness of current site documentation must be evaluated. The auditor's check for accuracy and completeness of site documentation must be carried out in conjunction with site inspections. Inspection of the site in relation to its description will determine if the documentation is inaccurate or incomplete and will serve as a check on the regional technicians to ensure they know the procedure for reporting site changes. Site inspections also evaluate the site in relation to the network's siting criteria. This evaluation must be a value judgement by the auditor, either in the form of a relative grading (e.g., excellent, good, marginal or unacceptable) or a stated opinion on the adequacy of the site for measuring inhalable particulate matter representative of the surrounding environs. Site evaluations are to be documented in the auditor's final report to the Particulate Sampling Committee. If sites are rated marginally acceptable or unacceptable by the auditor, the Particulate Sampling Committee must consider corrective action, such as, i) leaving the site as is, but documenting the reasons for its acceptance; ii) upgrading the site by making

upgrading the site by making physical changes to it; iii) initiating special studies at or near the site to quantitatively assess the magnitude of the problem; and iv) failing all else, relocate the site. It is the responsibility of the Network Coordinator to act upon these measures recommended in the auditor's report as well as updating site documentation, assessing the effects of the offending site on data representativeness and to determine why the differences were not detected as part of routine network operations.

The Field Operations component must also have its instrumentation and sample collection and handling procedures audited. The systems audit on this portion of the network operation is to consist of the following:

i) assessment of the completeness and accuracy of the Standard Operating Procedures and Technical Manual in relation to field instrumentation requirements and procedures and sample collection and handling procedures;

ii) assessment of the design, adequacy and effectiveness of the procurement and pre-testing, inventory control, calibration, preventive maintenance and routine checking and corrective action procedure;

iii) assessment of the adequacy of the network's instrumentation for meeting the network's overall objective and the network's quality assurance objectives with respect to accuracy, precision, completeness, representativeness and comparability.

The performance audit would consist of a quantitative assessment of the field instrumentation, namely:

i) on-site calibrations of all instruments;

ii) measurement of on-site operating conditions.

The major emphasis of external laboratory audits is placed on evaluating the laboratory's QA/QC procedures and their effectiveness in terms of meeting the network's requirements for quality assurance rather than a detailed investigation of each of the specific components within the laboratory system. As such, the audit will concentrate on evaluating the documentation of current operating procedures, QA/QC procedures and the QA responsibilities of the laboratory personnel involved.

Auditing of the data management component is limited in scope. The systems audit portion will concern itself with an assessment of the design, adequacy and effectiveness of the data screening and validation techniques used to flag data, if required. The effectiveness of the data screening and validation techniques is to be evaluated in a performance audit by, i) performing spot-checks on calculations used in the screening and validating process; and ii) inserting "dummy" data (unknown to the Database Scientist) into the database, performing the screening and validation checks on them, and determining if the appropriate qualifying remark codes are appended to these records.

All findings and recommendations of the external auditor's systems and performance audit are to appear in a final auditor's report to the Particulate Sampling Committee, who are to evaluate and act upon the report's recommendations, were appropriate and feasible.

5.6 QUALITY ASSURANCE REPORTING

Annually, a QA report is to be prepared by the Network Coordinator summarizing the results of the QA program over the preceding twelve-month period. This document is to report any information which will help determine the confidence that users may place in the data, the level of QA applied to the network, its effectiveness and recommendations on QA related problems. This report is an effective means of evaluating the costs of network quality assurance in terms of the increased data quality. The annual QA report is to be presented to the Particulate Sampling Committee for review and corrective action.

QA reports are to include the following specific information:

i) changes made to the QA Plan, QA Manual or the Standard Operating Procedures and Technical Manual;

ii) measures of data quality, namely:
   a) statistics of sample and data capture (completeness) and reasons for lost data;
   b) results of blank, replicate, blind and colocated sample analyses (precision and accuracy);
   c) laboratory QC data (precision, accuracy, comparability);
   d) results of special studies (precision, accuracy, comparability);

iii) significant QA problems, accomplishments, recommendations and corrective action to be taken;

iv) a synopsis of internal and external systems and performance audits;

v) status of data, including projected schedules for data reports;

vi) summary of QA training.

Upon review, QA reports are to be distributed to all network personnel and to all data users on the documentation distribution list.

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United States Environmental Protection Agency (1980) "Guidelines and Specification for Preparing Quality Assurance Project Plans - DRAFT", QAMS-005/80

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